



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

AMA1–RON2 Complex-Based Vaccine against Malaria

Description of Technology:

This technology relates to a malaria vaccine composed of a protein complex of Apical Membrane Antigen (AMA1) and rhoptry neck protein 2 (RON2) with an adjuvant.

AMA1 is a crucial component of the Plasmodium invasion machinery and is a leading

candidate for antimalarial vaccine development. AMA1-based vaccines have shown ability to block red cell invasion in in vitro assays, but protection has so far not translated to in vivo human infections. NIAID investigators have demonstrated that interaction between AMA1 and RON2 (or peptide thereof) is essential for malaria parasites to successfully enter human red blood cells (RBCs). Vaccination with un-complexed AMA1 and RON2 did not protect against lethal malaria. However, vaccination with a pre-formed AMA1– RON2 complex, highlighted in this technology, produced antibodies that protected against lethal malaria in an in vivo mouse model (P.yoelli) and blocked the entry of human malaria parasites into RBCs in vitro. Additionally, the inhibitory antibody response induced by the AMA1–RON2 complex was greater than AMA1 alone or when AMA1 and RON2 proteins were administered in a un-complexed form.

Immunization using the AMA1–RON2 complex of this technology represents a candidate for an effective malaria vaccine against multiple Plasmodium species.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Malaria vaccine

Competitive Advantages:

Lower-cost malarial prevention for developing/ developed countries.

Development Stage:

- Early-stage.

- In vitro data available.
- In vivo data available (animal).

Inventors: Prakash Srinivasan and Louis Miller (NIAID).

1. **Publications:** Srinivasan P, et al. Binding of Plasmodium merozoite proteins RON2 and AMA1 triggers commitment to invasion. Proc Natl Acad Sci U S A. 2011 Aug 9;108(32):13275–80. [PMID 21788485].
2. Srinivasan P, et al. Disrupting malaria parasite AMA1–RON2 interaction with a small molecule prevents erythrocyte invasion. Nat Commun. 2013;4:2261. [PMID 23907321].

Intellectual Property: HHS Reference No. E–066–2013/0—U.S. Provisional Application No. 61/841,479 filed 01 Jul 2013; PCT Application No. PCT/US2014/045065, filed July 1, 2014; European Application No. 14742116.8, filed July 1, 2014 (pending); U.S. Application No. 14/902,117, filed August December 30, 2015 (pending); and Chinese Application No. 201480037643.1, filed December 31, 2015 (pending).

Licensing Contact: Peter Tung, 240-669-5483; peter.tung@nih.gov. **Collaborative**

Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability and interest from parties interested in collaborative research to further develop, evaluate or commercialize AMA1–RON2 vaccine by providing well established human adjuvants and clinical trial funding. For collaboration opportunities, please contact Peter Tung, 240-669-5483; peter.tung@nih.gov.

Dated: February 24, 2017

Suzanne Frisbie

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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